



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3371-FN]

Medicare and Medicaid Programs: Approval of an Application from Accreditation Commission for Health Care, Inc for CMS Approval of its End Stage Renal Disease (ESRD) Facility Accreditation Program.

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our approval of the Accreditation Commission for Health Care, Inc (ACHC) for recognition as a national accrediting organization (AO) for End Stage Renal Disease (ESRD) Facilities that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this final notice is effective April 11, 2019 through April 11, 2023.

FOR FURTHER INFORMATION CONTACT: Tara Lemons, (410) 786-3030, Monda Shaver, (410) 786-3410 or Joann Fitzell (410) 786-4280.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an end stage renal disease (ESRD) facility, provided the facility meets the requirements established by the Secretary of the Department of Health and Human Services (the Secretary). Section 1881(b) of the Social Security Act (the Act) establishes distinct requirements for facilities

seeking designation as an ESRD facility under Medicare. Regulations concerning provider agreements and supplier approval are at 42 CFR part 489 and those pertaining to activities relating to the survey, certification, and enforcement procedures of suppliers, which include ESRD facilities are at 42 CFR part 488. The regulations at part 494 subparts A through D implement section 1881(b) of the Act, which specify the conditions that an ESRD facility must meet in order to participate in the Medicare program and the conditions for Medicare payment for ESRD facilities.

For an ESRD facility to enter into a provider agreement with the Medicare program, an ESRD facility must first be certified by a State survey agency as complying with the conditions or requirements set forth in section 1881(b) of the Act and our regulations at part 494 subparts A through D. Subsequently, the ESRD facility is subject to ongoing review by a State survey agency to determine whether it continues to meet the Medicare requirements. However, there is an alternative to State compliance surveys. Certification by a nationally recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if the Secretary finds that accreditation of a provider entity by an approved national accrediting organization (AO) meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may “deem” the provider entity to be in compliance. Accreditation by an AO is voluntary and is not required for Medicare participation.

Section 1865(a)(1) of the Act had historically excluded dialysis facilities from participating in Medicare via a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program; however, section 50404 of the Bipartisan Budget Act of 2018

(Pub. L. 115-123) amended section 1865(a) of the Act to include renal dialysis facilities as provider entities allowed to participate in Medicare through a CMS-approved accreditation program.

If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. An AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

II. Application Approval Process

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities that were not in compliance with the conditions or requirements; and their ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

III. Provisions of the Proposed Notice

On November 2, 2018, we published a proposed notice in the **Federal Register** announcing Accreditation Commission for Health Care, Inc.'s (ACHC's) request for approval of its Medicare ESRD facility accreditation program (83 FR 55172). In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of ACHC's Medicare ESRD Facility accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An onsite administrative review of ACHC's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ESRD facilities; and, (5) survey review and decision-making process for accreditation.

- A comparison of ACHC's Medicare accreditation program standards to our current Medicare ESRD facility Conditions for Coverage (CfCs).

- A documentation review of ACHC's survey process to do the following:

- ++ Determine the composition of the survey team, surveyor qualifications, and ACHC's ability to provide continuing surveyor training.

- ++ Compare ACHC's processes to those we require of State survey agencies, including periodic re-survey and the ability to investigate and respond appropriately to complaints against accredited ESRD Facilities.

- ++ Evaluate ACHC's procedures for monitoring ESRD Facilities it has found to be out

of compliance with ACHC's program requirements. This pertains only to monitoring procedures when ACHC identifies non-compliance. If non-compliance is identified by a State survey agency through a validation survey, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ Assess ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ Establish ACHC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of ACHC's staff and other resources.

++ Confirm ACHC's ability to provide adequate funding for performing required surveys.

++ Confirm ACHC's policies with respect to surveys being unannounced.

++ Obtain ACHC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the November 2, 2018, proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CfCs for ESRD facilities. No comments were received.

IV. Provisions of the Final Notice

A. Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared ACHC's ESRD facility accreditation requirements and survey process with

the Medicare CfCs at part 494, and the survey and certification process requirements of parts 488 and 489. ACHC's standards and standards crosswalk were also examined to ensure that the appropriate CMS regulations would be included in citations as appropriate. Our review and evaluation of ACHC's ESRD facility application, which was conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, ACHC has revised the following standards and certification processes:

- Section 494.30(a)(3) - (4), to ensure that its interpretive guidance includes HBV-specific procedures .
- Section 494.90(a)(7)(ii)(C), to ensure that its standard includes the full CMS regulatory reference.
- Section 494.100(c)(1)(iii), to ensure that its standard includes the full CMS regulatory reference.
- Section 494.100(c)(2), to ensure that its standards address requirements to ensure patient privacy.
- Section 494.110, to ensure that its standards address the complexity of the facility's organization.
- Section 494.120(c)(1)(iii), to correct the CMS reference noted in its standard.
- Section 494.170(c), to accurately reflect the federal requirements for retaining records when state statutes are less restrictive, and to ensure that its standard includes the full CMS regulatory reference.
- ACHC revised its policies, procedures and surveyor worksheets to ensure that survey documentation is consistently and accurately completed; contains sufficient detail; and provides

quantifiable information when appropriate.

- ACHC revised its policies and procedures to clearly delineate the criteria for determining the size and composition of its survey teams.
- ACHC revised its policies and procedures to ensure all deemed surveys remain unannounced.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that ACHC's ESRD facility accreditation program requirements meet or exceed our requirements, and its survey processes are also comparable. Therefore, we approve ACHC as a national accreditation organization for ESRD facilities that request participation in the Medicare program, effective April 11, 2019 through April 11, 2023.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Dated: April 5, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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